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TO: Commissioner Christine C. Ferguson and Members of the Public Health Council

THROUGH: Paul Dreyer, Ph.D. Associate Commissioner
Center for Quality Assurance and Control

FROM: Grant Carrow, Ph.D., Deputy Director
Center for Quality Assurance and Control

DATE: February 22, 2005

RE: Informational Memorandum Regarding Amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C

Introduction

The Drug Control Program proposes to amend regulations at 105 CMR 700.000 to establish standards for the possession and dispensing of contraceptive medications by family planning clinics and agencies. The regulations would require registration of family planning agencies that dispense contraceptive medications and would establish standards that would include, but not be limited to:

1. authorizing appropriately trained and supervised staff to supply medications;
2. training and monitoring authorized staff;
3. properly packaging and labeling medications;
4. reporting medication errors and adverse events; and
5. recordkeeping.

The amendments are expected to increase access to contraceptives and improve the reproductive health of patients.

The Drug Control Program intends to proceed to public hearing on the proposed changes to 105 CMR 700.000. The rationale for and approach to the proposed regulations are described in greater detail below. The proposed amendments are in Attachment A.

Overview

Family planning agencies often provide family planning services and contraceptives to traditionally underserved, uninsured populations. Many of the women served by these programs might not otherwise be able to obtain needed services. These providers have brought to the Department's attention a concern that underserved patients are encountering some obstacles to obtaining refills of contraceptives that could be ameliorated by enabling agencies to increase their capacity to supply refills.

Currently, the law permits only authorized prescribers, nurses and pharmacists to dispense these medications to patients. Many of the family planning sites, however, cannot afford to provide a practitioner on site, everyday, to provide a refill of these medications. It is also difficult to obtain such persons in geographically isolated areas or areas where it is difficult to recruit health care providers. Because there may not be a practitioner on site, women who come to the provider for family planning services may not be able to obtain a supply of contraceptives at that time. Their options are to come back another time or to seek the contraceptives from a pharmacy, which would require further time, effort and expense. These obstacles to access increase the chances that the patient will fail to obtain contraceptives in a timely fashion, with a correspondingly increased risk of an unplanned pregnancy.

Department staff have concluded that access to these medication refills needs to be expanded and that this expansion can be accomplished by allowing additional staff to provide refills with the appropriate protections to ensure patient health and safety. The provision of refills by staff should also have additional benefits, including increasing the number of patients receiving contraceptive services, decreasing waiting times for access to services, providing more culturally competent services and enabling clinical staff to spend more time providing clinical services to patients.

Regulatory Approach

The Drug Control and Family Planning Programs propose to permit family planning agencies to authorize staff, such as family planning counselors, medical assistants, clinic assistants and health educators, to provide refill supplies of contraceptives to patients. Family planning agencies would be required to obtain a Massachusetts Controlled Substances Registration for this purpose. The regulations would require medical oversight by a licensed practitioner. Moreover, the regulations would require additional safeguards, including written protocols and procedures, approved curricula and training, limited formulary, labeling requirements, counseling by the authorized prescriber, reporting of medication errors and adverse events, drug controls and maintenance of records. These requirements would ensure the safety of contraceptive refill dispensing by agency personnel.

Public Hearing

This is to notify the Public Health Council that the Drug Control Program plans to hold a public hearing on these proposed changes to 105 CMR 700.000 in March, 2005.

ATTACHMENT A

Proposal to Amend 105 CMR 700.000: Implementation of M.G.L. c. 94C

700.003 Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g).

700.003 – Add the following:

(H) Authorized employees and agents of a family planning clinic or agency ("agency") funded by the Department may engage in limited dispensing, only as provided by 105 CMR 700.003(H), of self administered oral, transdermal or intravaginal contraceptive medications in Schedule VI ("contraceptives").

(1) An agency may authorize the limited dispensing of contraceptives by designated employees and agents of the agency to clients of the agency, provided that the agency is registered with the Department pursuant to 105 CMR 700.004. Authorized employees and agents may include, but need not be limited to, family planning counselors, medical assistants, clinic assistants and health educators, unless otherwise specified in Department guidelines.
(2) Limited dispensing pursuant to 105 CMR 700.003(H) shall include:
    (a) selecting contraceptives in accordance with the prescription or order of an authorized prescriber;
    (b) labeling the package or container with the elements listed in 105 CMR 700.003(H)(7)(a); and
    (c) delivering the contraceptive to the ultimate user or agent of the ultimate user.
(3) The agency shall adopt and implement written policies and procedures authorizing such practice and ensuring safe and proper storage, handling and dispensing of contraceptives and compliance with 105 CMR 700.000.
(4) Limited dispensing shall be:
    (a) pursuant to the prescription or order of a licensed practitioner and in accordance with the policies and procedures of the agency and the Department; and
    (b) of refill prescriptions only.
(5) Only a physician, nurse practitioner, physician assistant or certified nurse-midwife authorized to prescribe, a registered nurse authorized by such physician, nurse practitioner, physician assistant or certified nurse-midwife or a pharmacist may dispense an initial supply of contraceptives. The authorized prescriber is responsible for offering to provide to the ultimate user, verbally or by other means acceptable to said user, clear directions for use and counseling on common adverse or severe side effects or interactions and therapeutic contraindications.
(6) The contraceptives shall be packaged in prefilled unit doses or units of use intended for self-administration by the patient. No more than a three month supply shall be provided at a visit when dispensed by an authorized employee or agent.
(7) Any contraceptives dispensed by a registered agency, including those dispensed by a practitioner, pharmacist, physician assistant, nurse or authorized employee or agent, shall be properly labeled.
    (a) A label shall be affixed to the outside of the package or container that includes at least the following:
        (i) authorized prescriber's name, address and telephone number;
        (ii) date of dispensing;
        (iii) name of the client; and
        (iv) initials of individual dispensing if other than the authorized prescriber;

(b) Unless already provided on the manufacturer's packaging, the following information must be added to the label by an authorized prescriber:
    (i) name, dosage form, strength and quantity of the contraceptives;
    (ii) clear, simple and brief directions for use and any necessary cautionary statements; and
    (iii) date on which the medication will expire; and
(c) If multiple packages of the same contraceptives are dispensed at the same time to the same ultimate user, the packages may be placed in a larger container to which the label containing the information required by 105 CMR 700.003(H)(7) has been affixed.

(8) The medical director of each registered agency shall:
(a) be the responsible person named on the registration of the agency;
(b) authorize and oversee the limited dispensing of contraceptives;
(c) authorize individual employees and agents of the agency to engage in limited dispensing;
(d) establish and enforce written policies and protocols, in accordance with any Department guidelines, to ensure:
    (i) proper storage, handling and dispensing of contraceptives, including routine quality assurance checks;
    (ii) reporting to the medical director and Department of issues related to the limited dispensing, administration or use of the contraceptives, including, but not necessarily limited to, medication errors and adverse events;
    (iii) appropriate documentation of written prescriptions or orders for medication dispensing;
    (iv) appropriate documentation of dispensing in client records and medication logs;
    (v) appropriate labeling of the dispensed contraceptives; and
    (vi) monitoring of compliance with these regulations;
(e) establish and enforce written policies and protocols to ensure that employees dispensing contraceptives are properly trained and current in their knowledge. Such employees shall be trained and certified in accordance with Department guidelines. Retraining and recertification shall be on at least an annual basis or as otherwise specified by the Department and shall include, but not be limited to:
    (i) verifying documentation of written prescriptions and medication orders;
    (ii) properly storing, handling and dispensing the contraceptives;
    (iii) properly documenting medication dispensing in accordance with agency policy;
    (iv) properly labeling the dispensed contraceptives;
    (v) identifying circumstances requiring consultation with the medical director; and
    (vi) complying with the other requirements of these regulations; and
(f) establish and enforce written policies and protocols to ensure that the agency maintains current and readily retrievable records of:
    (i) authorized employees who may dispense contraceptives in accordance with 105 CMR 700.003(H);
    (ii) staff trainings, evaluations and certifications;
    (iii) receipt and any return or disposal of contraceptives;
    (iv) logs of all contraceptives dispensed; and
    (v) medication errors and adverse events.

700.004: Registration Requirements

700.004(A) (2) – Add the following:

(V) Family Planning Agency

700.004 (C)(1)– Add the following:

(k) A family planning agency shall be registered solely for the purpose of possessing and dispensing contraceptive medications to clients of the agency, in accordance with 105 CMR 700.003(H).